



B6/B12DIV3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not Yet Assigned  
Group : 1804  
Applicant : Charles Weissmann  
Serial No. : 08/487,280  
Filed : June 7, 1995  
For: : DNA SEQUENCES, RECOMBINANT DNA MOLECULES  
AND PROCESSES FOR PRODUCING HUMAN-  
INTERFERON-LIKE POLYPEPTIDES

New York, New York  
September 27, 1996

Hon. Assistant Commissioner  
for Patents  
Washington, D.C. 20231

TRANSMITTAL LETTER FOR  
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure  
Statement in the above-identified application. This  
Statement is submitted:

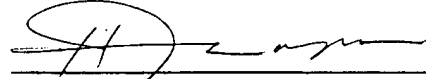
☐ within three months of the application filing  
date;

☒ more than three months from the application  
filing date but before the mailing date of the  
first Office Action on the merits.

In accordance with 37 C.F.R. § 1.98, submission of  
this Statement requires no fee. However, if for any reason  
a fee is due, the Commissioner is hereby authorized to  
charge payment of any fees required in connection with this  
Information Disclosure Statement to Deposit Account

No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,



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*Sept 27, 1996*  
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Name of Person Signing  
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Signature of Person Signing



#4  
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RECEIVED

OCT 8 1996

GROUP 1804

New York, New York  
September 27, 1996

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for Patents  
Washington, D.C. 20231

STATEMENT UNDER 37 C.F.R. §§ 1.56 AND 1.97

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97,  
applicants, through their attorney, wish to make of record  
the following documents. For the convenience of the  
Examiner, a completed Form PTO-1449, listing these  
documents, is attached.

United States patents

\*3,699,222  
4,184,917  
4,190,495  
\*4,237,224  
4,241,174  
\*4,262,090

\* This document may be relatively more pertinent than the  
other documents.



United States patent applications\*\*

801,343 (May 27, 1977)  
805,023 (June 9, 1977)  
849,591 (November 8, 1977)  
849,691 (November 8, 1977)  
849,692 (November 8, 1977)  
897,709 (April 19, 1978)  
897,710 (April 19, 1978)  
\*913,533 (June 8, 1978)  
41,909 (May 24, 1979)  
107,267 (December 26, 1979)

British patent specifications

1,412,591  
\*1,521,032  
1,568,047 (abstract only)\*\*\*  
2,019,408A  
2,027,033A  
2,031,434A  
\*2,033,905A  
2,034,323A  
2,034,717A  
\*2,037,296A

German patent applications

\*DT 2,724,918 (abstract only)  
DT 2,930,604 (abstract only)

European patent applications

1,929  
11,560  
\*18,218  
20,147  
\*28,033

Japanese patent applications

\*139,289/79  
\*33931/80

\*\* These applications were obtained in connection with the publication of various non-United States patent applications that claimed priority therefrom. In these cases, applicant has only cited one of the series of corresponding applications, usually the United States application. Should the Examiner desire any other information about a particular series of applications, applicant stands ready to provide it to him.

\*\*\* In those cases where less than the complete document is listed, it connotes that only the portion described is present in applicant's attorney's files. Should the Examiner desire further information about a particular document, applicant stands ready to assist him.



\_\_\_\_\_, Abstracts, Conference On Regulatory Functions Of Interferons", New York Academy of Sciences (October 23-26, 1979)

\_\_\_\_\_, "Purification Of Interferon mRNA By Hybridizing Induced Material to cDNA", Research Disclosure, No. 183009, pp. 361-62 (July 1979)

\* \_\_\_\_\_ Report "International Workshop On INTERFERON In The Treatment Of Cancer," (March-April 1975)

R. Ambler et al., "Partial Amino Acid Sequence Of Penicillinase Coded By Escherichia Coli Plasmid R6K", Proc. Natl. Acad. Sci. USA, 75, pp. 3732-36 (August 1978)

Berg et al. Conference On Regulatory Function Of Interferons, Abstract No. 19 (1979)

P. Beverley et al., "Killing Comes Naturally", Nature, 278, pp. 119-20 (March 8, 1979)

\*F. Bolivar et al., "Construction And Characterization Of New Cloning Vehicles II. A Multipurpose Cloning System", Gene, 2, pp. 95-113 (1977)

\*P. Bridgen et al., "Human Lymphoblastoid Interferon", J. Biol. Chem., 252, pp. 6585-87 (1977)

R. J. Britten and E. H. Davidson, "Repetitive And Non-Repetitive DNA Sequences And A Speculation On The Origins Of Evolutionary Novelty", The Quarterly Review of Biology, 46, pp. 111-133 (June 1971)

\*S. Broome et al., "Immunological Screening Method To Detect Specific Translation Products", Proc. Natl. Acad. Sci. USA, 75, pp. 2746-49 (June 1978)

C. Burrell et al., "Expression In Escherichia coli Of Hepatitis B Virus DNA Sequences Cloned In Plasmid pBR322", Nature, 279, pp. 43-47 (May 3, 1979)

M. Casadaban et al., "Lactose Genes Fused To Exogenous Promoters In One Step Using A Mu-Lac Bacteriophage: In Vivo Probe For Transcriptional Control Sequences", Proc. Natl. Acad. Sci. USA, 76, pp. 4530-33 (September 1979)

\*R. Cavalieri et al., "Synthesis Of Human Interferon By Xenopus Laevis Oocytes: Two Structural Genes For Interferons In Human Cells", Proc. Natl. Acad. Sci. USA, 74, pp. 3287-91 (August 1977)

A.C.Y. Chang et al., "Phenotypic Expression In E. coli Of A DNA Sequence Coding For Mouse Dihydrofolate Reductase", Nature, 275, pp. 617-24 (October 19, 1978)

\*P. Farrell et al., "Interferon Action: Two Distinct Pathways For Inhibition Of Protein Synthesis By Double-Stranded RNA", Proc. Natl. Acad. Sci. USA, 75, pp. 5893-97 (December 1978)

T.H. Fraser et al., "Chicken Ovalbumin Is Synthesized And Secreted By Escherichia coli", Proc. Natl. Acad. Sci. USA, 75, pp. 5936-40 (December 1978)

- A. Fritsch et al., "Clonage Du Genome Du Virus De L'hepatite B Dans Escherichia coli", C. R. Acad. Sc. Paris, 287, See D, pp. 1453-56 (December 18, 1978)
- \*J. Fujisawa et al., "Nonglycosylated Mouse L Cell Interferon Produced By The Action Of Tunicamycin", J. Biol. Chem., 253, pp. 8677-79 (1978)
- D. Goeddel et al., "Direct Expression In Escherichia Coli Of A DNA Sequence Coding For Human Growth Hormone", Nature, 281, pp. 544-48 (October 18, 1979)
- \*D. Goeddel et al., "The Structure Of Eight Distinct Cloned Human Leukocyte Interferon cDNAs", Nature, 290, pp. 20-26 (1981)
- D. Goeddel et al., "Expression In Escherichia coli Of Chemically Synthesized Genes For Human Insulin", Proc. Natl. Acad. Sci. USA, 76, pp. 106-10 (January 1979)
- \*M. Grunstein et al., "Colony Hybridization: A Method For The Isolation Of Cloned DNAs That Contain A Specific Gene", Proc. Natl. Acad. Sci. USA, 72, pp. 3961-65 (October 1975)
- \*E. Havell et al., "Altered Molecular Species Of Human Interferon Produced In The Presence Of Inhibitors Of Glycosylation", J. Biol. Chem., 252, pp. 4425-27 (1977)
- R. Herberman et al., "Augmentation By Interferon Of Human Natural And Antibody-Dependent Cell-Mediated Cytotoxicity", Nature, 277, pp. 221-23 (January 18, 1979)
- K. Itakura et al., "Expression In Escherichia Coli Of A Chemically Synthesized Gene For The Hormone Somatostatin", Science, 198, pp. 1056-63 (December 9, 1977)
- D. E. Kennell, "Principles And Practices Of Nucleic Acid Hybridization", Progr. Nucl. Acid Res. Mol. Biol., 11, pp. 259-301 (1971)
- \*I. Kerr et al., "pppA2'p5'A2'p5'A: An Inhibitor Of Protein Synthesis Synthesized With An Enzyme Fraction From Interferon-Treated Cells", Proc. Natl. Acad. Sci. USA, 75, pp. 256-60 (January 1978)
- \*E. Knight, Jr., "Interferon: Purification And Initial Characterization From Human Diploid Cells", Proc. Natl. Acad. Sci. USA, 73, pp. 520-23 (February 1976)
- J. Lewis et al., "Dual Action Of Double-Stranded RNA In Inhibiting Protein Synthesis In Extracts Of Interferon-Treated Mouse L Cells", Eur. J. Biochem., 86, pp. 497-509 (1978)
- \*N. Mantei et al., "The Nucleotide Sequence Of A Cloned Human Leukocyte Interferon cDNA", Gene, 10, pp. 1-10 (May 1980)
- J. Martial et al., "Human Growth Hormone: Complementary DNA Cloning And Expression In Bacteria", Science, 205, pp. 602-06 (August 10, 1979)
- \*A. Maxam et al., "A New Method For Sequencing DNA", Proc. Natl. Acad. Sci. USA, 74, pp. 560-64 (February 1977)

O. Mercereau-Puijalon et al., "Synthesis Of An Ovalbumin-Like Protein By Escherichia coli K12 Harboring A Recombinant Plasmid", Nature, 275, pp. 505-10 (October 12, 1978)

\*S. Nagata et al., "Synthesis In E. coli Of A Polypeptide With Human Leukocyte Interferon Activity", Nature, 284, pp. 316-20 (March 27, 1980)

\*S. Nagata et al., "The Structure Of One Of The Eight or More Distinct Chromosomal Genes For Human Interferon- $\alpha$ ", Nature, 287, pp. 401-08 (October 1980)

A. Rosenfeld, "Interferon: The Next Wonder Therapy?", The Reader's Digest, pp. 130-33 (November 1979)

F. Rougeon et al., "Insertion Of A Rabbit  $\beta$ -globin Gene Sequence In An E. coli Plasmid", Nucl. Acids Res., 2, pp. 2365-78 (December 1975)

\*M. Rubinstein et al., "Human Leukocyte Interferon Purified To Homogeneity", Science, 202, pp. 1289-90 (December 22, 1978)

\*M. Rubinstein et al., "Human Leukocyte Interferon: Production, Purification To Homogeneity, And Initial Characterization", Proc. Natl. Acad. Sci. USA, 76, pp. 640-44 (February 1979)

P.H. Seeburg et al., "Synthesis Of Growth Hormone By Bacteria", Nature, 276, pp. 795-98 (December 21/28, 1978)

J. Shine et al., "Construction And Analysis Of Recombinant DNA For Human Chorionic Somatomammotropin", Nature, 270, pp. 494-99 (December 8, 1977)

\*W. E. Stewart et al., "Comparisons of Several Biological and Physiochemical Properties of Human Leukocyte Interferons Produced By Human Leukocytes and E. coli", Gene, 11, pp. 181-86 (1980) [Chemical Abstracts, 94:63542q, p. 550 (March 1981)]

\*M. Streuli et al., "At Least Three Human Type  $\alpha$ -Interferons: Structure of  $\alpha 2$ " Science, 209, pp. 1343-47 (1980) [Chemical Abstracts, 93:236612x, p. 624 (December 1980)]

\*J. Sutcliffe, "Nucleotide Sequence Of The Ampicillin Resistance Gene Of Escherichia Coli Plasmid pBR322", Proc. Natl. Acad. Sci. USA, 75, pp. 3737-41 (August 1978)

\*T. Taniguchi et al., "Construction And Identification Of A Bacterial Plasmid Containing The Human Fibroblast Interferon Gene Sequence", Proc. Japan. Acad., 55, Ser. B, pp. 464-69 (1979)

\*T. Taniguchi et al., "Human Leukocyte And Fibroblast Interferons Are Structurally Related", Nature, 285, p. 547-49 (June 1980)

J. Treuner et al., "Successful Treatment Of Nasopharyngeal Carcinoma With Interferon", preprint

\*L. Villa-Komaroff et al., "A Bacterial Clone Synthesizing Proinsulin", Proc. Natl. Acad. Sci. USA, 75, pp. 3727-31 (August 1978)

R. Wagner, "Biological Studies Of Interferon I. Suppression Of Cellular Infection With Eastern Equine Encephalomyelitis Virus", Virology, 13, pp. 323-37 (1961)

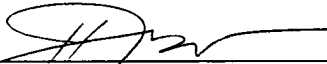
C. Weissmann, "The Cloning Of Interferon And Other Mistakes", Interferon (London), 3, pp. 101-134 (1981)

\*K. Zoon, "Amino Terminal Sequence Of The Major Component Of Human Lymphoblastoid Interferon", Science, 207, pp. 527-28 (February 1, 1980)

Pursuant to 37 C.F.R § 1.98(d), applicant has not enclosed copies of the above documents all of which were either cited by or submitted to the Examiner in United States Application Serial No. 06/118,084 (now patent 4,530,901) and/or in United States Application Serial No. 06/223,108 from which the instant application claims priority.

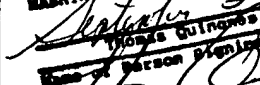
Applicant respectfully requests (1) that the Examiner fully consider these documents during the course of examination of this application; (2) that the "Notice of References Cited" issued in this application list these documents; and (3) that any patent issuing from the application contain a list of these documents.

Respectfully submitted,

  
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